IN THE UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
ANDERSON DIVISION
CIVIL ACTION NO. 8:16-cv-02688-BHH

Phillip Lamar West, Individually, and Karen Austin, Individually, and as Husband and Wife, Plaintiffs, vs. Sorin Group Deutschland GMBH and Sorin Group USA, Inc., Defendants.	**PLAINTIFFS' LOCAL CIVIL RULE 26.03 DISCLOSURES AND PROPOSED DISCOVERY PLAN**

Plaintiffs, by and through undersigned counsel, submit the following report pursuant to Fed. R. Civ. P. 26(f) and Local Civil Rule 26.03, D.S.C.:

I. RULE 26(F) CONFERENCE

Pursuant to Fed. R. Civ. P. 26(f), a telephonic meeting was held between the parties on Friday, January 6, 2017, and was attended by: Stephen Welch on behalf of the West plaintiffs, Blake Smith and Ashlee Winkler on behalf of the remainder of the plaintiffs, and Linda Svitak and Susan McWilliams on behalf of the defendants.

II. RULE 26(f)(1-4) RESPONSES

(1) What changes should be made in the timing, form, or requirement for disclosures under Rule 26(a), including a statement as to when disclosures under Rule 26(a)(1) were made or will be made?

Pursuant to the parties' Joint Motion to Extend Rule 26 Reporting Requirements and to Coordinate Pre-Trial Discovery ("Joint Motion") and the Court's October 31, 2016, Order granting the Joint Motion, the parties have agreed that Rule 26 disclosures should be made no later than January 9, 2017, with the exception of the exchange of documents pursuant to

Rule(a)(1). Defendants will make their documents pursuant to Rule 26(a)(1)(A)(ii) available on or before January 30, 2017. Moreover, the parties have agreed and the Court has ordered that these matters should be coordinated for pre-trial discovery. Accordingly, the form of the parties' Rule 26 disclosures will be changed to make appropriate disclosures both generally and as to each of the matters that have been consolidated.

(2) The subjects on which discovery may be needed, when discovery should be completed, and whether discovery should be conducted in phases or be limited to or focused upon particular issues.

Plaintiffs believe that discovery will be needed on the following subjects:

a. The design, manufacture, and sale of the Sorin 3T heater-cooler units at issue including the knowledge by Defendants of the problems and defects at the time of application to the U.S. government for approval for use in the U.S. and any subsequent problems which developed;

b. The medical care received by each Plaintiff before and after the surgery during which the Sorin 3T heater-cooler unit was used;

c. Plaintiff's medical history for a reasonable time period from before the date of the surgery to the present time, if applicable, including any and all pre-existing medical conditions; and

d. Facts surrounding each Plaintiff's activities before and after the surgical procedure during which each Plaintiff was exposed to a Sorin 3T heater- cooler unit.

Plaintiffs reserve the right to supplement this response or to seek additional discovery as may be deemed appropriate. The parties have agreed that fact discovery should be completed no later than January 8, 2018, with the understanding that, if unexpected issues arise, the parties may need additional time for discovery. The parties do not believe that discovery should be conducted in phases or be limited to, or focused upon, particular issues.

(3) What changes should be made in the limitations on discovery imposed under these rules or by local rule, and what other limitations should be imposed.

The parties agree that no limitations on discovery other than those already contained in the Federal Rules of Civil Procedure need be imposed. Absent agreement of counsel, discovery requests will be limited to 25 interrogatories per party and plaintiffs will request a total of 50 interrogatories per defendant.

(4) Any other orders that should be entered by the court under Rule 26(c) or under Rule 16(b) and (c).

Contemporaneously with these Rule 26.03 disclosures, the parties will file a proposed Amended Conference and Scheduling Order for the Court's consideration. Additionally, the parties will agree to a reasonable protective order to preserve the confidentiality of Defendants' trade secrets and proprietary information pursuant to Rule 26(c)(1)(G) and will be circulating a proposed protective order to counsel for consideration shortly.

III. LOCAL CIVIL RULE 26.03 DISCLOSURES

Plaintiffs, by and through their undersigned counsel, submit the following report pursuant to Local Civil Rule 26.03, D.S.C.:

(1) Short Statement of the Facts of the Case

The Defendants market and sell thermal regulator devices to be used on patients in the operating room, including the Sorin 3T Heater-Cooler System ("Sorin 3T System"). Prior to May 5, 2014, the Defendants manufactured, introduced, and/or delivered for introduction into interstate commerce, the Sorin 3T System. The Sorin 3T System is intended to provide temperature-controlled water to heat exchanger devices (cardio-pulmonary bypass heat exchangers, cardioplegia heat exchangers, and thermal regulating blankets) to warm or cool a patient during cardio-pulmonary bypass procedures lasting six (6) hours or less. The Sorin 3T

System is a Class II Medical Device that is subject to the Food and Drug Administration's ("FDA") Section 510K premarket notification process ("510K" or "510K process"). Before commercial distribution in the United States of the Sorin 3T System, the Defendants submitted a 510K premarket notification of intent to market the Sorin 3T System with the Secretary of Health and Human Services for FDA approval. The FDA determined that the Sorin 3T System was substantially equivalent to legally marketed predicate devices that do not require approval of a premarket approval ("PMA") application. This determination was relayed to the Defendants via letter on June 6, 2006, 510K number K052601. Essentially, the 510k process differs from the PMA process in how carefully the FDA examines the safety of the medical device. The PMA process is required for Class III medical devices while Class I and Class II predicate medical devices can be approved through the less rigorous 510K process. The FDA approval allows the Defendants to commercially distribute the Sorin 3T System in accordance with the conditions and regulations described in the approval letter. Any commercial distribution of the Sorin 3T System that does not comply with the conditions set forth in the letter are violations of the Federal Food, Drug, and Cosmetic Act ("the Act"). Generally, the manufacturer must comply with all of the Act's requirements, including but not limited to: "Registration and Listing (21CFR part 807); Labeling (21CFR part 801); Good Manufacturing Practice Requirements as set forth in the Quality Systems Regulation (21CFR part 820); and if applicable, the Electronic Product Radiation Control Provisions (Sections 531-542 of the Act); 21CFR 1000-1050."

On or about June 20, 2014, GHS publically announced that approximately 14 patients had tested positive for a rare non-tuberculosis mycobacterium infection, known as Mycobacterium abscessus ("*M. abscessus*"). The majority of those patients were exposed to the bacterium during open heart surgeries. At that time, GHS indicated that there had been three (3) deaths resulting from the same infection. On or about June 26, 2014, GHS released a second statement indicating that there were 15 confirmed cases of patients with the infection. On July 21, 2014, GHS confirmed that the patient death toll had increased to four (4).

In the July 21, 2014 announcement, GHS stated that it sent out letters to "…approximately 180 patients on whom specific cardiopulmonary surgical equipment had been used" since those patients were at risk after potentially being exposed to the *M. abscessus* bacterium, including Plaintiff West.

Investigations were undertaken by the South Carolina Department of Health and Environmental Control (SC DHEC) in an effort to determine the cause(s) for the *M. abscessus* infection outbreak at GHS. On July 21, 2014, prior to the recall on the Sorin 3T System, SC DHEC released a statement that outlined specific measures that needed to be immediately implemented at GHS as it related to the "cardioplegia machine." On July 15, 2015, the FDA issued a Class II Recall of the Sorin 3T System due to the "potential colonization of organisms, including Mycobacteria, in Sorin Heater-Cooler Devices, if proper disinfection and maintenance is not performed per instructions for use."

On December 29, 2015, the FDA issued a Warning Letter to the Defendants, which indicated that its inspection of Sorin's Germany and Colorado facilities revealed that the Sorin 3T System devices had been "adulterated," meaning the "methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation [were] not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820."

Defendants' Sorin 3T System was used during Plaintiff West's aortic valve replacement and Cardiac Bypass Grafting Procedure, performed at GHS, on or about May 5, 2014, wherein the Plaintiff West's surgeon, Dr. Barry Davis, used the device to assist in the cooling and re-warming of Plaintiff West's blood. Plaintiff West was subsequently discharged from the hospital.

Over the following days and weeks, Plaintiff West's condition began to deteriorate. Initially, while there were no observable signs of infection initially around the incision site, Plaintiff West began running a high-grade fever, displayed signs of increasing weakness, and developed pneumonia. On or about June 17, 2014, Plaintiff West began treatment at GHS for a red rash around his sternal wound and an area toward the superior aspect of his incision that appeared to be swollen and contain fluid. Plaintiff West was placed on antibiotics and scheduled to undergo sternal debridement by Dr. Davis. Plaintiff West underwent the sternal debridement, was fitted with a wound vac, and was continued on the antibiotics while the wound contents were cultured. Plaintiff West had to undergo additional debridement, as well as a pectoralis major muscle flap procedure, which has severely affected the use of his arm. The wound cultured out Mycobacteria. Plaintiff West was discharged home with the wound vac, and was scheduled for home health care, as well as regular treatment by an Infectious Disease physician in addition to his cardiologist and a thoracic surgeon. On or about July 24, 2014, Plaintiff West was readmitted to GHS for delayed healing of his surgical wound. While attempting to dress his wound, nurses found pus bubbling from the tissue at the incision site.

Due to the severity of Plaintiff West's wound dehiscence and exposure of wires and sutures, he was again taken for a sternal debridement and wound flap procedure review. All of the sutures and wiring had to be redone. Blood cultures were positive for gram-positive cocci. Plaintiff West had contracted the *M. abscessus* infection and was placed on additional antibiotics. Plaintiff West continued treatment for the *M. abscessus* sternal wound infection, and was either hospitalized or received treatment at a physician's office in August, September, October, November and December of 2014, as well as January and February of 2015. Plaintiff West's treatment by physicians for this *M. abscessus* infection is ongoing.

(2) Names of Fact Witnesses and Brief Summary of Expected Testimony

Plaintiff Phillip Lamar West. Mr. West will have knowledge of his claimed injuries and damages, his medical and health condition before and after cardiac surgery, the nature and extent of his current impairment (if any), any current symptoms of infection, communications with his healthcare providers and hospitals, communications with anyone about potential exposure to any bacteria, including but not limited to NTM, and the means for this exposure, whether he requires any treatment for his alleged injuries, communications with any governmental investigators, and communications with Defendants.

Plaintiff Karen Austin West. Ms. West will have knowledge of her claimed injuries and damages, Mr. West's medical and health condition before and after cardiac surgery, any current symptoms of infection, communications with his healthcare providers and hospitals, communications with anyone about potential exposure to any bacteria, including but not limited NTM, and the means for this exposure, whether he requires any treatment for his alleged injuries, communications with any governmental investigators, and communications with Defendants.

Mr. West's treating physicians, especially Barry Davis, M.D. of 890 West Faris Road, Greenville, SC. Such individuals may have discoverable information regarding Mr. West's medical and health condition before and after cardiac surgery, the nature and extent of his current impairment (if any), the conditions in the operating room at the time of surgery, the heater-cooler used and its condition, any recommended treatment for potential NTM exposure, and communications with Defendants, government agencies, and/or the Greenville Health System Hospital. It may include doctors, nurses, medical staff, and risk management staff at GHS.

Thierry Dupoux, Vice President Quality Assurance, c/o Defendants' counsel. Mr. Dupoux may have discoverable information regarding the design, manufacture, operation, and/or sale of the Sorin 3T heater-cooler unit and other allegations in Plaintiffs' pleadings.

Christian Peis, Director Quality Assurance, c/o Defendants' counsel. Mr. Peis may have discoverable information regarding the design, manufacture, operation, and/or sale of the Sorin 3T heater-cooler unit and other allegations in Plaintiffs' pleadings.

Bryan Olin, Senior Vice President Clinical, Quality, and Regulatory Affairs, c/o Defendants' counsel. Mr. Olin may have discoverable information regarding the design, manufacture, operation, and/or sale of the Sorin3T heater-cooler unit and other allegations in Plaintiffs' pleadings.

Shanna Schmidt, Product Manager. Ms. Schmidt may have discoverable information regarding the design, manufacture, operation, and/or sale of the Sorin 3T heater-cooler unit and other allegations in Plaintiffs' pleadings.

Other current and former employees of either Defendant may have information concerning the design, development, testing, regulatory history, compliance, quality assurance, manufacturing, marketing, and sales of the Sorin 3T Systems alleged to have been used in Plaintiffs' surgeries.

Employees of the federal or state government that may have knowledge or information related to the regulatory approval of the Sorin 3-T for use in the U.S., or information related to the Mycobacteria outbreak at GHS.

Plaintiffs reserve the right to supplement this response. By way of further response, Plaintiffs incorporate by reference any and all witnesses named by any Defendant and expressly reserve the right to call such witnesses.

(3) Name(s) and Subject Matter of Expert Witness(es)

John H. Jarrell, PhD, PE.
Biomechanical Engineering

Carl Joseph Gisnarian, MS CCP
Perfusionist

In addition, Plaintiffs anticipate that expert witnesses in various fields, including engineering, medicine, epidemiology, surgery, and microbiology will be required to address issues related to the design and manufacture of the Sorin 3T heater-cooler unit, general and specific causation, and the medical conditions and claimed injuries of the Plaintiffs.

(4) Summary of Claims

Count I – Negligence in design, labeling manufacturing, assembly, inspection, testing, marketing, distribution, instruction, and/or sale, pursuant to S.C. Code § 15-73-10 *et seq.*; *Rife v. Hitachi Const. Mach. Co., Ltd.*, 363 S.C. 209, 609 S.E.2d 565 (Ct. App. 2005); *Bragg v. Hi-Ranger, Inc.*, 319 S.C. 531, 462 S.E.2d 321 (Ct. App. 1995), and other case law.

Count II – Strict products liability in the sale of the product in a defective and/or unreasonably dangerous condition, pursuant to S.C. Code § 15-73-10 *et seq.*; *Rife v. Hitachi Const. Mach. Co., Ltd.*, 363 S.C. 209, 609 S.E.2d 565 (Ct. App. 2005); *Bragg v. Hi-Ranger, Inc.*, 319 S.C. 531, 462 S.E.2d 321 (Ct. App. 1995), and other case law.

Count III – Breach of express warranty pursuant to S.C. Code § 36-2-101 *et seq.*

Count IV – Breach of implied warranties pursuant to S.C. Code § 36-2-101 *et seq.*

Count V – Negligent misrepresentation pursuant to 21 U.S.C. § 360 *et seq.*, 21 CFR Part 803, and other associated regulations, *McLaughlin v. Williams*, 379 S.C. 451, 665 S.E.2d 667 (Ct. App. 2008) and other case law.

Count VI – Misrepresentation by omission pursuant to 21 U.S.C. § 360 *et seq.*, 21 CFR Part 803, and other associated regulations.

Count VII – Violation of the S.C. Unfair Trade Practices Act pursuant to S.C. Code § 39-5-20.

Count VIII – Loss of Consortium pursuant to S.C. Code § 15-75-20 and South Carolina common law.

(5) Absent special instructions from the assigned judge, the parties shall propose dates for the following listed in Local Rule 16.02.

a. Exchange of FED. R. CIV. P. 26(a)(2) expert disclosure;

The parties agree to exchange expert disclosures as follows:

For the Plaintiff: February 12, 2018
For the Defendant: March 26, 2018

b. Completion of discovery.

The parties agree fact discovery shall be completed in this case by January 8, 2018, and expert discovery shall be completed by May 7, 2018.

(6) Special Circumstances

None.

(7) Additional Information Requested in Pre-Scheduling Order

None.

Respectfully submitted,

McGowan Hood & Felder, LLC

s/ J. Stephen Welch

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January 11, 2017